UNITED STATE . DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/418,887	10/15/99	COHEN M	5967.US.D1

023492
ABBOTT LABORATORIES
DEPT. 377 - AP6D-2
100 ABBOTT PARK ROAD
ABBOTT PARK IL 60064-6050

HM12/1019

EXAMINER	
DAVIS,N	
ART UNIT	PAPER NUMBER
1642	8

DATE MAILED: 10/19/01

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/418,887	COHEN ET AL.	
	Examiner	Art Unit	
	Natalie A. Davis	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-31* is/are pending in the application.

4a) Of the above claim(s) *31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The Group Art Unit examiner of the application **has been changed**. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Dr. Natalie A. Davis**.

Applicant's amendment filed 16 July 2001 (Paper No: 7) is acknowledged. Accordingly, claims 10-20 are cancelled and claims 21-31 are new. Claims 21-31 are pending. The examiner has elected to examine species SEQ ID NO:2. Claims 21-30 are being examined, while claim 30 is withdrawn from examination as being drawn to a non-elected invention.

Information Disclosure Statement

The information disclosure statement filed 15 October 2000 has been considered. A signed copy is attached hereto.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 21-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting a target polynucleotide using the polynucleotide of SEQ ID NO:2, does not reasonably provide enablement for detection using degenerate coding sequences of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

3. Factors to be considered in determining whether undue experimentation is required, are summarized in *Ex parte* Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

4. The claims are drawn to a test kit useful for detecting a target polynucleotide in a sample comprising a container containing the polynucleotide of SEQ ID NO: 2, complete complements and degenerate coding sequences thereof.

5. The specification states that the present invention provides a method of detecting a target PS112 polynucleotide in a test sample, which comprises contacting the test sample with a polynucleotide specific for PS112 and detecting the presence of PS112.

6. Lehninger, et al. (Principles of Biochemistry, 2nd Ed., Worth Publishers, NY, 1993) is cited in order to establish the general state of the art and the level of predictability of hybridization. Lehninger, et al. teach that hybridization requires the pairing of nucleotide bases of two nucleic acid strands which are complementary (p. 343) and teaches that complementary strands are not identical in either base pair sequence or composition, that is wherever adenine appears in one chain, thymidine is found in the other and wherever guanine appears in one chain, cytosine is found in the other (p. 335). Applicant has not taught how to hybridize identical nucleic acid strands or for example a degenerate strand of SEQ ID NO:2 to that of SEQ ID NO:2, one to the other. In view of the Lehninger, et al. teaching, one of ordinary skill in the art would not clearly expect to be able to hybridize two identical nucleic acid strands one to the other or a degenerate strand of SEQ ID NO:2 to SEQ ID NO:2. In addition, there are many polynucleotides with degenerate coding sequences of SEQ ID NO:2 that may or may not function as a probe to detect target polynucleotides. Due to degeneracy the polynucleotide may only be 33% identical or complementary to the polynucleotide to be detected (SEQ ID NO:2), and the specification does not give any guidance to which molecules having at least 33% sequence identity to SEQ ID NO:2 will function as the claimed. Thus, it would be an undue burden to one of ordinary skill in the art to assay for claimed sequences, which are capable of functioning as contemplated. One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to any polynucleotide that is at least 33% identical to SEQ ID NO: 2 and applicant has not enabled all of these types of modifications because it has not been shown that these polynucleotides are capable of functioning as that which is being disclosed.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 21-30 are rejected under the judicially created doctrine of double patenting over claims 1-6 of U. S. Patent No. 5,919,638 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Even though the conflicting claims are not identical, they are not patentably distinct from one another because the claims are both drawn to a polynucleotide of SEQ ID NO: 2 and a method of making the polynucleotide. Even though claims 21 and 22 recites a test kit useful for detecting a target polynucleotide, the scope of the claim is drawn to a polynucleotide of SEQ ID NO:2, which is covered by U. S. Patent No. 5,919,638. The tools used to collect tissue, in claim 22, are no different from standard protocols and gives little weight to the claim.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony

Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, Ph.D.
October 8, 2001

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600